

Office Action Summary

Application No.
09/077,718

Applicant(s)
Nyqvist et al.

Examiner
Taofiq Solola

Group Art Unit
1613



Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

☒ Claim(s) 1-18 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1613

Claims 1-18 are pending in this application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. It is not clear if the claims are drawn to processes of making or methods of use.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The term "medical disturbances" in claim 13, line 2, and the term "related medical disturbances" in claim 12, lines 1-2, are not defined in the specification so as to ascertain the

Art Unit: 1613

medical disorders that are included and/or excluded by the term. The few listed "related medical disturbances" on page 3, lines 6-8 of the specification are indicated as examples only. Therefore, it is not possible to determine the meet and bounds of the term as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 7, 12-13 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-13 are rejected for reasons set forth above under 35 U.S.C. 112, first paragraph.

Claims 4, 7 and 17 recite the limitation "crystalline form", "therapy" and "process for the manufacture of" in claim 4, line 1; claim 7, line 1 and claim 17, line 1, respectively. There is insufficient antecedent basis for these limitations in the claims. The salts of claims 1-3 are not described in the specification as amorphous and the examples in the specification are obtained only in the crystalline form. The salts in claims 1-3 are therefore assumed to be in crystalline form only.

Art Unit: 1613

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evenden et al., WO 95/11891.

Applicants claim tartaric salts of (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide, their composition and method of use for the treatment of CNS disorders. Evenden et al., teach similar compounds having general formula I (page 5, lines 1-20); their organic and inorganic acids salt including salts of hydrochloric and tartaric acids (page 7, line 7) and their pharmaceutical preparations (compositions). See page 11, lines 1-11. The difference between the instant invention and that of Evenden et al., is in the generic descriptions of the claimed compounds (salts). Therefore, the instantly claimed invention is prima facie obvious from the teaching of Evenden et al., because the indiscriminate selection of "some" among "many" is prima facie obvious. In re Lemin, 141 USPQ 814. The motivation to make the claimed compounds is to make additional compounds useful for treating CNS disorders.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evenden et al., WO 95/11891.

Art Unit: 1613

Applicants claim a process of making tartaric salts of (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide comprising dissolving (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide in an aqueous or non-aqueous organic solution of tartaric acid. Evenden et al., teach similar compounds having general formula I (page 5, lines 1-20), and a process of making their salts comprising adding ether solution of the compounds to a second ether solution of hydrochloric acid. Evenden et al., also teach that tartaric acid could be used to make the salts (page 7, line 7). The difference between the instant invention and that of Evenden et al., is in the generic descriptions of the claimed compounds (salts). Therefore, the instant invention is prima facie obvious from the teaching of Evenden et al., because the indiscriminate selection of "some" among "many" is prima facie obvious. In re Lemin, 141 USPQ 814. The motivation is to make additional salts useful for treating CNS disorders.

Objection

Claim 17 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Title

Art Unit: 1613

Title

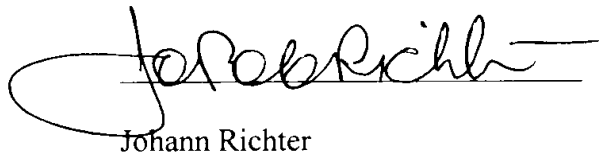
The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola whose telephone number is (703) 308-4690.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Johann Richter, can be reached on (703) 308-4532. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Johann Richter', is written over a horizontal line. The signature is stylized with a large loop at the beginning and a long horizontal stroke at the end.

Johann Richter

Supervisory Patent Examiner

Group 1613